UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Diane O'Neil

v.

Case No. 20-cv-175-PB
Opinion No. 2022 DNH 121

Somatics, LLC

MEMORANDUM AND ORDER

Diane O'Neil is seeking damages from Somatics, LLC, for injuries she alleges were suffered while undergoing electroconvulsive therapy (ECT) at Elliot Hospital. The ECT device that O'Neil's doctors used to treat her was produced and sold to Elliot by Somatics. Somatics has challenged O'Neil's claims in a motion for summary judgment.

I. BACKGROUND

A. O'Neil's ECT Treatment

O'Neil was suffering from severe treatment-resistant depression when her treating psychiatrist, Dr. David Ledner, referred her to Elliot Hospital for observation and an ECT consult. O'Neil was admitted on August 17, 2016. Her admitting psychiatrist, Dr. A. J. Ramirez, performed a psychiatric consult and physical examination. O'Neil's medical records state that she was feeling "pretty depressed" then and believed that ECT would be a reasonable

alternative to continuing with medications that were not alleviating her symptoms. O'Neil Dep., Doc. No. 52-4, 70.

A few days later, O'Neil had her initial ECT consultation with Dr. Reinhard Viehoff. See Viehoff Session Notes, Doc. No. 52-5; ECT Authorization, Doc. No. 52-6. During the consultation, O'Neil confirmed that she had watched an informational film provided by Elliot about ECT. Dr. Viehoff also noted that O'Neil appeared to be "knowledgeable" about ECT and the risks and benefits associated with it. See id. at 68. O'Neil recalls only reading positive things about ECT before her treatments. See O'Neil Dep., Doc. No. 52-4, 29.

Dr. Viehoff wrote in his notes that he discussed "the risk and benefits of [ECT]" with O'Neil, including a "1/10,000 death rate, seizure cardiac issues, dental complications, [and] cognitive side effects." See Viehoff Dep., Doc. No. 52-3, 23. They also discussed how Dr. Viehoff might approach her treatments. One option they discussed was bitemporal electrode placement, which "works more rapidly" but "may have more cognitive side effects" than right unilateral electrode placement, which "may not be as effective . . . [and] would require more treatments, and is associated with less cognitive side effects." See id.

Dr. Viehoff also outlined various cognitive risk factors associated with ECT. He noted that patients could experience "a spotty memory" or "difficulty recalling the events around the time of the hospitalization, the inpatient

treatments, [and] the initial index course" and "may have to relearn information that they previously knew." See id. at 24. For example, ECT might force a patient to "relearn a specific piece of information," such as "where something is at a grocery store or a phone number." See Viehoff Dep., Doc. No. 61-1, 25–26. Still, the patient would "absolutely" be able to "retain that information going forward" after relearning it. See id. Dr. Viehoff also typically warned that cognitive side effects might extend for "weeks to months" but would "generally" go away. See Viehoff Dep., Doc. No. 52-3, 13, 24; Doc. No. 61-1, 27. To color what he meant by "permeant memory loss," Dr. Viehoff ordinarily gave "the example of [a] patient [he] knew who had [a] trip to Hawaii" that he "didn't recall." See id. at 35–36. Such "memory deficits" are "not usual," Dr. Viehoff would be sure to emphasize. See id. It is unclear how else, if at all, Dr. Viehoff warned O'Neil about the risk of permanent memory loss. See id. at 34, 94.

O'Neil ultimately agreed to proceed with bitemporal ECT with "the requisite monitoring of the cognitive [screening] evaluation pretreatment on an inpatient basis." See id.; 8.22 Consultation Notes, Doc. No. 52-5, 4. O'Neil signed an ECT Authorization form that same day. See ECT Authorization, Doc. No. 52-6.

The Authorization form cautioned that "[a]s with all forms of medical treatment, there is a possibility of some side effects of treatment." Id. That is,

some patients, after undergoing ECT, "report difficulty remembering some things such as the names of friends, dates, or other facts." Id. Those cognitive effects "normally" clear up "within four weeks after the last treatment." Id. It states that a patient might also expect "a headache, muscle soreness, or nausea." Id. Other side effects could include "[m]inor irregularities in heart rate and rhythm"; "[v]ery rarely, myocardial infarction (heart attack) or stroke"; "extremely rarely," "[d]islocations or bone fractures"; and "a slight risk of damage to fragile teeth." Id. "To reduce the risk of medical complications," the form explained that O'Neil would "receive a careful medical evaluation prior to starting ECT." Id.

Between August 2016 and February 2017, O'Neil underwent 22 bitemporal ECT sessions. As her treatments got underway, O'Neil's memory issues started to present themselves. During an October 2016 meeting with Dr. Ledner after her sixth treatment, O'Neil reported mild short-term memory impairment but also that her depression symptoms were improving. See Ledner Dep., Doc. No. 52-8, 33. Dr. Ledner expected that her memory impairment "would resolve over time after the cessation of the ECT treatments." See Ledner Dep., Doc. No. 61-3, 23. But about a month after her last session, O'Neil informed Dr. Ledner that she was "off all of her medications" and had "decided to stop ECT because she could not tolerate the memory impairment that went with it." See id. at 38.

B. Somatics's ECT Devices

The ECT device that Dr. Viehoff used to treat O'Neil is known as the Thymatron IV. Somatics manufactured the device and sold it to Elliot in December 2005.

Before acquiring the Thymatron IV, Elliot used an older Somatics ECT device, the DGx, which it bought in 1999. See Swartz Dec., Doc No. 51-3, ¶ 6. Somatics provided two copies of its 1996 ECT Instruction Manual along with the DGx. See id. The 1996 Manual included a warning about potential side effects of ECT, such as "cognitive and memory dysfunction." See 1996 Manual, Doc. No. 51-4, 5–6. It noted that memory loss could consist of both "a retrograde amnesia that is more pronounced for most recent events, and an anterograde amnesia for events that occur during or shortly after the course of ECT." See id. The 1996 Manual also explained that while "many patients receiving ECT experience improved memory . . ., a few have complained of persistent memory or cognitive impairment months or years later." Id. And for those "few" patients, "memory loss might result from concurrent antidepressant medication, residual depression, progression of pre-existing brain disease, or effects of ECT itself." See id. The 1996 Manual also noted that although two studies had reported "[p]ersistent memory deficits for autobiographical (personal) events lasting at least six months," "no such deficits have been reported after brief pulse unilateral ECT." See id.

When Somatics sold Elliot the Thymatron IV, it supplied the hospital with copies of the eleventh edition of its Thymatron Instruction Manual, published in 2005. See Swartz Dec., Doc. No. 51-3, ¶ 7. Unlike the 1996 Manual, the 2005 Manual did not include a substantive "side effects" section. Instead, it merely recommended "that doctors planning to use the [Thymatron] read and follow the recommendations of the Task Force Report of the American Psychiatric Association as set forth in 'The Practice of Electroconvulsive Therapy (American Psychiatric Association, 2001) [("APA Task Force Report")]." See 2005 Manual, Doc. No. 51-5, 2–3.

The APA Task Force Report is over three hundred pages long, and, among other things, it does describe potential negative ECT side effects. It explains how:

> A small minority of patients treated with ECT later report devastating cognitive consequences. Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad aspects of cognitive function are so impaired that the patients are no longer able to engage in former occupations. Because these subjective reports of profound cognitive deficits are rare, determination of their absolute base rates is difficult. Multiple factors likely contribute to these perceptions by former patients.
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> [S]ome patients' self-reports of profound ECT-induced deficits may reflect objective loss of function. As noted, as with the adverse effects of any medical intervention, individual differences occur in the magnitude and persistence of ECT's cognitive effects. In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years before the treatment[.]

Id. at 14–15. The APA Task Force Report also identifies how for some patients, "the recovery from retrograde amnesia will be incomplete, and evidence has shown that ECT can result in persistent or permanent memory loss." Id. at 13. While O'Neil's doctors were somewhat familiar with the APA Task Force Report, they were generally unfamiliar with the 2005 Manual, but they were confident that they would have reviewed it. See Viehoff Dep., Doc. No. 52-3, 63; Schwartz Dep., Doc. No.52-7, 8–9. And while Somatics updated its instruction manual many times between 2005 and 2016, Elliot did not keep detailed records of which manuals it possessed. See Elliot Responses, Doc. No. 51-23, 1–2.

In 2018, after O'Neil's ECT treatments, Somatics updated its Thymatron manual to include updated warnings about ECT's side effects. The new manual warned that "ECT may result in anterograde or retrograde amnesia. Such post-treatment amnesia typically dissipates over time; however, incomplete recovery is possible. In rare cases, patients may experience permanent memory loss or permanent brain damage." See 2018 Regulatory Update, Doc. No. 60-19, 5. And in its revised Thymatron Manual, Somatics included an addendum entitled "Instructions to Patient," in all-caps, bolded font. Under the heading "Safety Information," Somatics added three warnings adorned with large graphics:

⚠ WARNING When used as intended, this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.

⚠ WARNING ECT device use may be associated with disorientation, confusion, and memory problems.

See User Manual v21, Doc. No. 51-6, 7–8. Beneath those warnings, Somatics added guidance surpassing the sparse proviso included in the 2005 Manual:

> ECT treatment may be associated with disorientation, confusion and memory loss, including short-term (anterograde) and long-term (autobiographical) memory loss following treatment. Based on the majority of clinical evidence, these side effects tend to go away within a few days to a few months after the last treatment with ECT. Although the incidence of permanent cognitive memory loss was not supported by the clinical literature, some patients have reported a permanent loss of memories of personal life events (i.e., autobiographical memory).
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> Patients treated with ECT may experience manic symptoms (including euphoria and/or irritability, impulsivity, racing thoughts, distractibility, grandiosity, increased activity, talkativeness, and decreased need for sleep) or a worsening of the psychiatric symptoms they are being treated for. Depressed patients have committed suicide even after ECT. Partial decrease in depression may increase risk of suicide. . . .

See id.

C. The Complaint

O'Neil filed her complaint in January 2020. See Compl., Doc. No. 1. She alleges that her ECT treatments did not produce any improvement in her underlying depression but caused her to suffer "sustained brain damage, neurocognitive injuries and permanent memory loss in addition to other

physical, physiological, psychological and emotional injuries and harms, as well as lost earnings and loss of earning capacity." Id. ¶¶ 60–61. She asserts seven claims for relief: Count I - negligence; Count II - strict liability; Count III - breach of implied warranty of fitness; Count IV - breach of implied warranty of merchantability; Count V - breach of express warranty; Count VI - violation of the New Hampshire Consumer Protection Act; and Count VII - fraud. Somatics challenged all seven counts in a motion for summary judgment. In response, O'Neil gave up on her warranty claims but otherwise defended her claims for relief.

II. STANDARD OF REVIEW

Summary judgment motions are granted when the record leaves "no genuine dispute as to any material fact." Fed. R. Civ. P. 56(a); Tang v. Citizens Bank, N.A., 821 F.3d 206, 215 (1st Cir. 2016). A fact is "material" when it has the "potential to affect the outcome of the suit." See Cherkaoui v. City of Quincy, 877 F.3d 14, 23 (1st Cir. 2017). A "genuine dispute" exists if a reasonable jury could resolve the disputed fact in the nonmovant's favor. See Ellis v. Fidelity Mgmt. Tr. Co., 883 F.3d 1, 7 (1st Cir. 2018). In deciding this motion, a district court cannot engage in "differential factfinding" and is limited to making "an essentially legal determination." McCarthy v. Nw. Airlines, Inc., 56 F.3d 313, 315 (1st Cir. 1995). In doing so, I must "view the

entire record in the light most hospitable to the party opposing summary judgment, indulging all reasonable inferences in that party's favor." See id.

The moving party must present evidence that "it believes demonstrates the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If the moving party satisfies this requirement, the burden shifts to the nonmoving party to identify specific facts showing that there is a genuine issue for trial and to "demonstrate that a trier of fact could reasonably resolve that issue in its favor." Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 853 (1st Cir. 2016).

III. ANALYSIS

Somatics has launched a multi-pronged attack on O'Neil's negligence, strict liability, Consumer Protection Act, and fraud claims. I begin with its challenges to the negligence claim.

A. Negligence

O'Neil alleges that Somatics was negligent because it failed to adequately investigate reports of adverse events from the use of ECT; failed to adequately report adverse ECT events to the FDA; and violated the Federal Food, Drug, and Cosmetic Act (FDCA), see 21 U.S.C. § 301 et seq., as amended by the Medical Device Amendments of 1976 (MDA), see Pub. L. 94-

295.[1] O'Neil also faults Somatics for failing to adequately warn of the dangers of ECT. Somatics argues in response that O'Neil's negligence claim is preempted by the FDCA and that her negligent failure to warn claim is not supported by sufficient evidence.

1. Preemption

The Supreme Court has considered the preemptive effect of the FDCA in a trio of cases. In Medtronics v. Lohr, 518 U.S. 470 (1996), the Court first addressed the FDCA's express preemption provision, which provides that:

> [N]o state . . . may establish or continue with respect to a device intended for human use any requirement —
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> (2) which is different from, or in addition to, any requirement applicable under this chapter to the device and
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> (2) which relates to the safety or effectiveness of the device or to any other requirement applicable to the device under this chapter.

See 21 U.S.C. § 360k(a).

At issue in Lohr were state-law tort claims resulting from alleged defects in a pacemaker authorized for sale under a limited FDA review process known as "§ 510(k) review." 518 U.S. at 492–93. Unlike other new and potentially harmful medical devices subject to a more exacting

[1] O'Neil also asserts that Somatics negligently failed to "research, test, and analyze their ECT device," but Somatics does not challenge this negligence theory.

"premarket approval" (PMA) process, a manufacturer of a device subject to § 510(k) review need only establish that its device is "substantially equivalent" to devices already on the market. Id. at 480, 492–93. In concluding that Lohr's common law tort claims were not preempted by § 360k, the Court held that § 510(k) review ordinarily does not result in federal device-specific "requirements" that expressly preempt state-law tort claims. Id. at 494, 501.

In Buckman Company v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), the Court explained that state-law tort claims could also be impliedly preempted when they conflict with the objectives of the FDCA. In that case, a manufacturer of orthopedic bone screws obtained § 510(k) approval to market its product for certain specified uses. After problems developed with the bone screws, actions were filed against the manufacturer alleging state-law fraud on the FDA claims. In concluding that the state-law fraud claims were impliedly preempted, the Court emphasized that the claims "exist solely by virtue of the FDCA disclosure requirements" and that the existence of the requirements "is a critical element in [the plaintiffs'] case." Id. at 353. The Court also highlighted the FDCA's language in § 337(a), specifying that all "proceedings for the enforcement, or the registration violations of this chapter shall be by and in the name of the United States." Id. at 349 n.4 (quoting 21 U.S.C. § 337(a)). Finally, the Court explained that preemption was required

because it would otherwise allow states to interfere with the enforcement discretion that the FDA needed to fulfill its enforcement duties. Id. at 348.

Finally, in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), the Court returned to the FDCA's express preemption provision and clarified its holding in Lohr. In that case, a balloon catheter that had been approved for use after undergoing PMA review ruptured during a coronary angioplasty procedure. The plaintiff asserted state-law negligence, strict liability, and breach of warranty claims. The manufacturer argued in response that § 360k(a) expressly preempted the state-law claims. In examining the manufacturer's argument, the Court employed a two-part test. First, it asked whether the FDCA had established any federal "requirements" for the device. Second, it considered whether the state-law causes of action imposed requirements that were "different from or in addition to" the federal requirements. Id. at 321–22.

The Court began its analysis of the first question by distinguishing Lohr, where the Court held that the state-law claims were not preempted because the device at issue had been approved for use after § 510(k) review. Id. at 322–23. As the Court explained, the situation in Riegel was different because the balloon catheter that had allegedly injured the plaintiff had been approved for use after PMA review. Id. Because PMA review requires the FDA to assess a product's safety and effectiveness, the Court reasoned that

any conditions on the agency's approval of the device as a part of the PMA process were necessarily device-specific requirements that expressly preempt additional or inconsistent state-law requirements. Id. The court then answered the second question by concluding that even general state-law requirements will be preempted if they add to or conflict with any federal requirements. Id. at 327–28. Because the plaintiffs' state-law tort claims conflicted with requirements the FDA established for the catheter as a part of the PMA approval process, the state-law claims were expressly preempted. Id. at 330.

In a recent First Circuit decision not cited by either party, the court explained how express preemption under Lohr and Riegel works with implied preemption under Buckman to limit the types of state-law tort claims involving medical devices that can escape preemption. See Plourde v. Sorin Grp. USA, Inc., 23 F.3d 29 (1st Cir. 2022). The court explained that express and implied preemption combine to:

> leave plaintiffs with a 'narrow gap through which their state-law claim must fit if it is to escape express or implied preemption: the plaintiffs must be suing for conduct that violates the FDCA (or else their claim is expressly preempted by § 360(k) but [they] must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted by § 337(a)).'

Id. at 33 (quoting Dumont v. Reilly Foods Co., 934 F.3d 35, 42 (1st Cir. 2019)) (cleaned up).

When addressing Somatics's preemption arguments, I apply the court's guidance in Plourde with two minor points of clarification. First, this case differs from Plourde because the product at issue there had undergone PMA review. See Plourde v. Sorin Grp. USA, Inc., 2018 WL 1542361 *2 (D. Mass. 2018). Accordingly, under Riegel, any PMA-specific directives by the FDA that the manufacturer in Plourde needed to comply with were clearly "requirements" that would expressly preempt any additional or inconsistent requirements in state tort law. Here, in contrast, Somatics's ECT device was subject to § 510(k) review. As the Court recognized in Lohr, directives that emerge from § 510(k) review do not automatically qualify as "requirements" that can lead to express preemption. See 518 U.S. at 501. Accordingly, I will not assume that O'Neil's tort claims are expressly preempted only because they impose requirements that were not imposed by federal law.

Second, when applying Plourde to implied preemption claims, I read Buckman to hold that state tort claims are impliedly preempted unless they would remain viable even if the FDCA had never been enacted. In other words, a state cannot adopt a negligence claim that can survive preemption under Buckman if that claim itself depends on the FDCA.

Somatics presents both implied preemption and express preemption attacks on O'Neil's negligence claim. I address each of its arguments in turn.

i. Implied Preemption

Somatics argues that O'Neil's negligence claim is impliedly preempted if it alleges that Somatics is liable for violating federal laws governing medical device manufacturers, see Compl., Doc. No. 1, ¶ 64(v), failing to report adverse events to the FDA, see id. ¶ 64(iv), and failing to investigate reports of adverse events, see id. ¶ 64(iii).

O'Neil tries to save these claims by noting that "the New Hampshire Supreme Court has long treated a violation of state or federal statutes or regulations as evidence of negligence." See Obj., Doc. No. 60, 16. While this is true in general, it cannot defeat an implied preemption claim under Buckman. If a state-law cause of action depends solely on the breach of a requirement established by the FDCA, it is impliedly preempted even if the state has a general practice of looking to federal statutory and regulatory requirements for the standard of care in negligence cases. Here, O'Neil's claim that Somatics is liable under state law for disregarding federal statutes and regulations is the precise claim that Buckman said was impliedly preempted. See 531 U.S. at 347–48.

Somatics is on less firm ground when it asserts that other aspects of O'Neil's negligence claim are impliedly preempted. To the extent that O'Neil argues that Somatics was negligent for failing to adequately investigate reports of adverse events from the use of ECT, her claim is clearly not

preempted because it is grounded in state tort law that does not depend on any federal requirement. Further, while her claim that Somatics was negligent for failing to report adverse events to the FDA is a closer call, I cannot grant summary judgment on that claim either because Somatics has not sufficiently developed the legal theory on which its argument depends. See Celotex, 477 U.S. at 327.

In Plourde, the parties disagreed as to whether a state-law failure to report adverse events claim to the FDA was preempted by the FDCA. In attempting to resolve the disagreement, the court determined that it needed to know whether Massachusetts law recognizes an independent state-law claim for negligence based on a failure to report adverse events to the FDA. 23 F.4th at 37. Because it was unclear whether Massachusetts law recognizes such a claim, the court certified the issue to the Massachusetts Supreme Judicial Court. Id. In another case not cited by the parties, the Second Circuit followed the same path. See Glover v. Bausch & Lomb Inc., 6 F.4th 229, 233 (2d Cir. 2021). In response, the Connecticut Supreme Court explained that its state law did indeed recognize a duty to report adverse events to regulators. See Glover v. Bausch & Lomb Inc., 343 Conn. 513, 557 (2022).

The New Hampshire Supreme Court has not expressly recognized a state-law duty to report adverse events to regulators. Nor has it determined that no such duty exists under state law. Because the parties have not

adequately briefed this issue in light of Plourde, I decline Somatics's request to resolve it without additional briefing.

ii. **Express Preemption**

Somatics also argues that O'Neil's attempt to base her negligence claim on a failure to warn of the risk of brain injury from ECT is expressly preempted. Somatics bases its argument on a 2018 final order by the FDA reclassifying ECT devices from Class III to Class II for certain purposes. See 83 Fed. Reg. 66121. According to Somatics, the reclassification order establishes new labeling requirements for ECT devices that mandate warnings of specified risks associated with ECT that do not include brain injury among the identified risks. Somatics argues that the new warnings are device-specific "requirements" that expressly preempt any state-law claim for relief that could require additional warnings.

O'Neil responded to this argument in part by arguing that even if the 2018 reclassification order could be understood to establish device-specific warning requirements, "Somatics has not explained how or why the actions of the FDA in 2018 in passing the final order . . . are relevant for preemption purposes for events that transpired in 2016 (O'Neil's ECT was in 2016)." See Obj., Doc. No. 60, 20. Although Somatics filed a reply brief addressing many of O'Neil's arguments, it failed to present a satisfactory response to this

argument. For this reason alone, its request for summary judgment on this issue must be denied.[2]

2. Failure to Warn

As I have noted, O'Neil bases her negligence claim in part on her contention that Somatics failed to adequately warn of certain risks of using its ECT device. Somatics responds by invoking the learned intermediary doctrine and presenting multiple reasons why it believes that O'Neil's failure to warn claim is defective. Somatics is not entitled to summary judgment on the failure to warn claim because its arguments depend on material facts that remain in genuine dispute.

As one of my colleagues has recently explained, "the learned intermediary doctrine holds that a manufacturer's duty to warn regarding the risks associated with a product runs to a patient's treating physician (or another learned intermediary) rather than directly to the patient." Luna v. Atrium Med. Corp., 561 F. Supp. 3d 62, 69 (D.N.H. 2021). Although the New Hampshire Supreme Court has not yet applied the learned intermediary doctrine to medical device claims, I have no doubt that the court will follow

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[2] Somatics also asserts without offering any supporting reasoning that O'Neil's strict liability claim is expressly preempted to the extent that it asserts that all ECT devices are unreasonably dangerous and defective. Somatics, however, has not adequately identified the device-specific requirement that supports its argument. This failure is fatal to its argument.

the many courts in other jurisdictions that have applied the doctrine in medical device cases. See, e.g., Plourde, 23 F.4th at 36 (Massachusetts law); Salinero v. Johnson & Johnson, 995 F.3d 959, 964–65 (11th Cir. 2021) (Florida law); Ideas v. Teva Pharm. USA, Inc., 986 F.3d 1098, 1101 (8th Cir. 2021) (Nebraska law); Kaiser v. Johnson & Johnson, 947 F.3d 996, 1015 (7th Cir. 2020) (Indiana law); Bard IUC Filters Product Liability Litig., 969 F.3d 1067, 1076 (9th Cir. 2020) (Georgia law). Accordingly, I assume for purposes of analysis that Somatics is correct in claiming that the learned intermediary doctrine applies here.

Building on the learned intermediary doctrine, Somatics argues that: (1) its warnings were adequate as a matter of law; (2) any failure on its part to give adequate warnings could not have caused O'Neil's injury because her doctors did not rely on Somatics's warnings; (3) any warnings by Somatics were inconsequential because O'Neil's doctors were already aware of the risks of ECT; and (4) O'Neil accepted the risk that she would be injured by receiving ECT treatment. The fatal flaw in all these arguments is that they turn on material facts that remain in genuine dispute. Accordingly, Somatics is not entitled to prevail on any of its arguments for summary judgment.

B. Strict Liability

Somatics argues that it is entitled to summary judgment on O'Neil's strict liability claim "because she has produced no evidence of any manufacturing defect in Somatics's ECT device or any specific design defect that rendered it unreasonably dangerous." Def.'s Mot., Doc. No. 51-1, 25. It bases this argument on the New Hampshire Supreme Court's decision in Buckingham v. Reynolds, 142 N.H. 822 (1998), when the court held that to prove a strict liability claim, a plaintiff must prove that the product is both unreasonably dangerous and that it is defective. Id. at 826. According to Somatics, O'Neil's claim fails this test because she alleges only that its ECT device is unreasonably dangerous without offering any separate evidence that it is defective.

I decline to grant Somatics the relief it seeks because its argument misreads O'Neil's strict liability claim. Notwithstanding Somatics's argument to the contrary, O'Neil has identified multiple alleged defects with the Thymatron that cause it to be unreasonably dangerous. O'Neil argues that the device — when used in accordance with Somatics's instructions — likely administers "well above six times" the electrical dose necessary to stimulate an adequate seizure. See Castleman Expert Rep., Doc. No. 57-39, 6–7. And according to O'Neil's expert, the amount of dosage administered by the Thymatron is set arbitrarily based on the age of the patient. See id. at 5–6.

The more voltage the machine administers, the greater the risk of cellular damage. See id. at 8. Another alleged defect is the Thymatron's allowance for bilateral ECT. O'Neil claims that the Thymatron is more dangerous than if it relied only on unilateral ECT. See Read Expert Rep., Doc. No. 57-41, 5. Despite Somatics's protestations, these properly alleged defects prevent me from granting summary judgment on O'Neil's strict liability claim.[3]

C. Consumer Protection Act and Fraud Claims

Somatics also seeks summary judgment on O'Neil's Consumer Protection Act ("CPA") and common law fraud claims (Counts VI and VII). I agree with Somatics that O'Neil has failed to identify sufficient supporting evidence to sustain either claim.

O'Neil bases both her CPA claim and her fraud claim on essentially the same legal theory. Her core contention, which she repeats verbatim in both counts, is that Somatics falsely represented to the public "that its Thymatron

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[3] O'Neil also bases her strict liability claim on a failure to warn theory. The New Hampshire Supreme Court has recognized that a product can be deemed unreasonably dangerous and defective "if the design of a product makes a warning necessary to avoid an unreasonable risk of harm from a foreseeable use . . . ." Chellman v. SAAB-Scania AB, 138 N.H. 73, 78 (1993); see also Cheshire Med. Center v. W.R. Grace & Co., 49 F.3d 26, 29 (1st Cir. 1995) ("It is settled law in New Hampshire that strict liability for product defect includes manufacturing defect, design defect, and warning defect."). Somatics's argument would not undermine O'Neil's failure to warn strict liability claim even if she could not support her claim on other grounds.

ECT Device was 'the safest and most effective treatment for severe depression'" and that it did not cause brain injury, permanent memory loss, long-term or persistent effects on intellectual abilities or memories; and "other similar warranties of safety and efficiency." Compl., Doc. No. 1, ¶ 100 (CPA Claim); ¶ 109 (Fraud Claim). Because both claims sound in fraud, O'Neil must ordinarily satisfy the particularity requirements of Fed. R. Civ. P. 9(b). See, e.g., N. Am. Catholic Educ. Programming Fund., Inc. v. Cardinale, 567 F.3d 8, 15 (1st Cir. 2009); N.H. Elec. Cooperative, Inc. v. Elster Sols., LLC, 2017 WL 2861667, at *3 (D.N.H. 2017).

O'Neil failed to plead either claim with the particularity required by Rule 9(b). Moreover, in her response to Somatics's summary judgment motion, the only specific misrepresentation she cites comes from a Patient Information Pamphlet that Somatics apparently released in 2002. Even if I assume for purposes of analysis that this statement she cites qualifies as an actionable misrepresentation or omission, she has cited no evidence that would support a finding either that the statement was made with the requisite scienter or that it was relied on by O'Neil or her doctors. These deficits are fatal to her CPA and fraud claims.

IV. CONCLUSION

Somatics's motion for summary judgment (Doc. No. 51) is granted in full as to Counts III, IV, VI, and VII. Its motion is granted as to Count I only as to O'Neil's claim that Somatics was negligent for the reasons set forth in paragraph 64(v) of her complaint. In all other respects, the motion is denied.

SO ORDERED.

/s/ Paul J. Barbadoro
Paul J. Barbadoro
United States District Judge

September 30, 2022

cc: Counsel of Record